

REMARKS

Claims 1-30 were examined. All claims were rejected for allegedly lacking enablement. Applicants wish to thank Examiner Moran and Examiner Clow for the helpful telephone interview of August 18, 2004. Applicants agree with the summary of the interview as described in the Interview Summary, mailed August 17, 2004.

I. Status of the Claims

Support for the amendments is indicated by paragraph number, referring to the published patent application.

Applicants have amended claim 1. Support for the term "one or more physio-chemical property" finds support in paragraph 23 of the specification. The physio-chemical properties specified in step (c) are those identified by the Examiner in page 3 of the Office Action as enabled by the specification. The amendments to steps (e), (f) and (g) find support in paragraph 202 of the specification and in original claim 22 (now canceled). Accordingly, these amendments do not add new matter.

Claim 5 has been amended to correct usage.

Claims 15 and 16 have been amended for consistency with amended claim

1.

New claims 31-36 find support in paragraph 97.

New claims 37-51 find support in paragraph 115 and paragraphs 157-172.

New claim 54 finds support in paragraph 100.

New claim 53 finds support in paragraphs 8, 95, and 219.

II. Specification Objection

The Examiner objected to the specification for containing embedded hyperlinks. Applicants have amended the specification to delete the links.

III. Claim Objection

The Examiner objected to claim 5 as containing a typographical error. Applicants have amended the claims to correct the typographical error.

IV. Claim Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-16, 18-28 and 30 stand rejected under 35 U.S.C. § 112, first paragraph on the grounds that the specification does not reasonably provide enablement for any physio-chemical property used for fractionation of polypeptides. The Examiner stated that the specification provides enablement for properties such as amino acid sequence, molecular weight, isoelectric point, hydrophobicity, hydrophilicity, glycosylation, phosphorylation, epitope sequence, ligand binding sequence, charge at a specified pH, and metal chelate binding. Applicants request reconsideration.

Without agreeing that the specification does not enable fractionation based on properties other than the ones identified by the Examiner above, and in order to facilitate prosecution, Applicants have amended the claims to recite the physio-chemical properties for which the Examiner has stated that the specification does provide enablement. Applicants do so without prejudice to pursue such matter elsewhere. Applicants request the Examiner to withdraw the rejection.

Claims 1-30 stand further rejected for lack of enablement as failing to comply with the enablement requirement. The examiner stated that the practice of the invention involved undue experimentation.

During the interview, the Examiner stated that as written, the practice of the invention as claimed did not result in unambiguous identification of a polypeptide.

The Examiner further stated that the phrase, “identifying a physio-chemical property,” excluded the identification of, and fractionation based on, more than one physio-chemical property. Applicants disagree that the term “a” is limiting. However, in order to advance prosecution, Applicants have amended the claim to refer to “one or more” physio-chemical properties.

In her rejection, the Examiner stated that the specification does not define how one goes from the step of generating a gene expression profile of mRNA that is expressed to identifying a physio-chemical property of an encoded polypeptide. Applicants have amended claim 1 to make it clear that this step involves determining the amino acid sequence of the polypeptide encoded by the mRNA and deriving the physio-chemical property from the amino acid sequence.

The Examiner further stated that there is no strict correlation between gene expression and protein expression. Applicants recognized this fact in paragraph 8 of the specification. The step in claim 1 of “correlating” implicitly recognizes that the fractionated proteins may or may not contain a polypeptide encoded by the mRNA. Indeed that is one of the utilities of the invention – the ability to correlate mRNA expression with protein expression.

The Examiner stated in the interview that many fractionation techniques would result in more than one protein having the physio-chemical property, and, therefore, the method as claimed would not unambiguously identify the encoded polypeptide from among the fractionated polypeptides. Applicants believe that the ability to identify candidate polypeptides, whether or not the polypeptide encoded by the mRNA is definitively identified among these, is highly useful information for the practitioner. Nevertheless, in order to advance prosecution, Applicants have amended step (e) of claim 1. The additional steps of the amended claim – selecting one or more candidate polypeptides, determining its/their identity and correlating the identity or identities with the encoded polypeptide – address this issue. The amendment adds no new matter, as it finds support in the specification in paragraph 202, as well as original claim 22, which Applicants have accordingly canceled.

Applicants further point out that affinity capture of an analyte, e.g., with an antibody, followed by mass spectrometry allows essentially unambiguous identification of the analyte.

For these reasons, Applicants respectfully request the Examiner to withdraw the rejections and speed this application to allowance and issue.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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